LIBRAMEDICAL

1. 510(K) SUMMARY

1.1 ADMINISTRATIVE INFORMATION

Date of Summary Preparation: 23-October-2013

Submitter/Manufacturer:

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Submission Contact:

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1.2 DEVICE NAME

Device Name:	InterValve V8 Transluminal BAV Catheter
Common Name:	Balloon Aortic Valvuloplasty Catheter
Classification Name:	Catheter, Balloon Aortic Valvuloplasty
Product Code:	OZT
Regulation Number:	21CFR870.1250
Device Class:	II

1.3 PREDICATE DEVICES

The device is substantially equivalent to the InterValve V8 Transluminal BAV Catheter (**K123111**) and the NuMed NuCLEUS-X BAV Catheter (**K082776**).

1.4 DEVICE DESCRIPTION

The V8 Transluminal BAV Catheter System features an hour-glass shaped dilatation balloon on the distal end of a catheter. The catheter is inserted through a percutaneous entry site into the common femoral artery via an introducer sheath and advanced retrograde to the aortic valve. The catheter is always delivered over a guidewire. The balloon is then inflated to dilate the stenotic aortic valve leaflets in an effort to increase valve opening dimensions and systemic blood flow by improving leaflet mobility. The hour-glass shaped balloon with the undersized waist segment is intended to minimize over-dilatation of the valve annulus while allowing the full dilation of the valve leaflet. The bulbous proximal balloon segment is appropriately sized for the patient's aortic root dimensions to maximize valve leaflet opening.

1.5 INDICATIONS FOR USE / INTENDED USE

The V8 Transluminal BAV Catheter is indicated for Balloon Aortic Valvuloplasty.

There is no change in intended use. The indication for use and intended use are identical to the predicate devices.

1.6 TECHNOLOGICAL CHARACTERISTICS

The V8 balloon is made of clear non-compliant polymeric material. The balloon is available in four diameter sizes (22mm, 24mm, 26mm and 28mm). The waist of the hour-glass balloon is sized such that it is smaller than the bulb diameter up to the rated burst pressure.

The catheter is available in standard working lengths (107cm – 113cm) and is compatible with a 12F or 14F introducer sheath. It is introduced through the femoral artery via the introducer sheath and tracked over a 0.035" wire. The catheter's inner shaft beneath the balloon is marked with radiopaque platinum iridium marker bands, one at the center of the waist, and one each at the outside edges of the proximal and distal balloon shoulders. The catheter is packaged in a heat sealed Tyvek pouch and provided sterilized. It is intended for single use only. These characteristics are identical to the predicate V8 device (K123111).

1.7 PERFORMANCE DATA

The relevant design verification testing was repeated. These tests included all bonds and balloon characteristics of the redesigned balloon. There is no change in materials or the overall design of the device. Therefore, the biocompatibility data and catheter performance data from the predicate device cleared under K123111 is applicable. The results demonstrated that the device functions as intended.

The clinical experience used to support the change to the device labeling indicates that the change does not affect the safety and effectiveness profile of the device. Predicate device clinical experience showed that physicians may or may not employ the use of concomitant rapid ventricular pacing. The revised wording on the device labeling was changed to be consistent with how the devices are used by physicians, giving the physician the discretion with respect to the use of rapid

ventricular pacing during balloon placement. Therefore, the data support the modification to the device instructions for use.

1.8 SUBSTANTIAL EQUIVALENCE

The V8 device covered by this submission is substantially equivalent to the predicate devices. There is no change in the indication for use or intended use.

The slight modifications to the 24mm and 26mm nylon balloons do not change the balloon technological characteristics. The new dimensions are within the bounds of the original dimensions and characteristics of the balloons initially cleared (K123111). The new dimensions do not change the technological characteristics of the new V8 devices compared with the predicate V8 devices.

The revised wording on the device labeling was changed to be consistent with how the devices are used by physicians, giving the physician the discretion with respect to the use of rapid ventricular pacing during balloon placement. This is similar to the predicate devices and is accepted practice in the industry.

The V8 device in this submission has the same intended use, and the same technological characteristics as the previously cleared predicate devices. The minor differences between this device and its predicates do not raise new questions of safety or efficacy

1.9 CONCLUSION

The modified V8 Transluminal BAV Catheter System (K132728) is substantially equivalent to the predicate devices (K123111 and K082776) in materials, function and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 22, 2013

InterValve, Inc.
c/o Dr. Sew-Wah Tay, Ph.D.
CEO/President & Regulatory Consultant
Libra Medical Inc.
84801 73rd Avenue North, Suite 63
Minneapolis, MN 55428

Re: K132728
Trade/Device Name: V8 Transluminal BAV Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Balloon Aortic Valvuloplasty Catheter
Regulatory Class: Class II
Product Code: OZT
Dated: October 23, 2013
Received: October 24, 2013

Dear Dr. Tay,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Center for Devices and Radiological Health

Enclosure

7. INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number (if known): K132728

Device Name: V8 Transluminal BAV Catheter

Indications for Use:
The V8 Transluminal BAV Catheter is indicated for Balloon Aortic Valvuloplasty.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)